DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HC1-35

60 8th Street, N.E.
Atlanta, Georgia 30309

July 30, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warren E. Hauck, Owner
Diversified Healthcare Services
11525 N. Fulton Industrial Blvd.
P.O. Box 1065
Alpharetta, Georgia 30004

WARNING LETTER

Dear Mr. Hauck:

An inspection of your drug repackaging facility was conducted between June 30 and July 7, 1997, by Investigator Leah M. Andrews. The inspection revealed numerous significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMPs), as set forth in Title 21 of the Code of Federal Regulations (21CFR), Part 211. These deviations cause your repacked drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The current inspection was initiated in response to a recall of product which had been mislabeled at your facility. The inspection revealed several additional instances where similar repackaging errors had occurred. You have failed to implement appropriate controls to ensure the prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products. You failed to document any inspection of the packaging and labeling areas immediately before use to assure that all drug products have been removed from previous operations. Inspection should also be made after packaging and labeling operations have concluded. The results of these inspections should be documented in the batch production records. Examples of records which failed to include this information include the recalled lot and the three lots with labeling errors brought to your attention by [redacted]

You have failed to routinely determine the actual yield and percentages of theoretical yield at the conclusion of each appropriate phase of processing and packaging. Such calculations should be performed by one person and independently verified by a second person. Examples where this was not done include the lots discussed above. The obvious yield discrepancies in the products involved in the recall should have initiated an investigation if they had been evaluated at the appropriate time. You have also failed to establish any maximum or minimum limits for the yield determinations.

You have failed to implement a procedure for drug product inspection after repackaging. No documentation was available that packaged and labeled product is examined after packaging to provide assurance that the containers in the lot have the correct label. A representative sample of units shall be collected at the completion of packaging and must be visually examined for correct labeling. These results should be recorded in the batch production records. Reserve samples were not being retained for each packaging run. You had not implemented any procedures addressing the periodic examination of these retained drug samples. You have failed to maintain any documentation to indicate that incoming drug products, containers, closures, and labeling are sampled and examined prior to being released into inventory. There was no indication that drug products are ever physically examined prior to use.

You failed to properly store labels for your various drug products. Labels and other labeling materials for each different drug product, strength, or quantity of content should be stored separately with suitable identification. The investigator noted the storage of [redacted] and [redacted] labels immediately adjacent to each other. You failed to control the labeling printed by your firm in the dispense medication operation. There was no documentation available to indicate that these labels were examined prior to use. In addition there were no records indicating the quantity printed, amount utilized, or subsequently destroyed.

You could provide no assurance that all repacked drug products meet applicable standards of identity, strength, quality, and purity throughout their labeled expiration date. You could not provide documentation to substantiate the expiration dates (or lack thereof) on the liquid products you were repacking. The [redacted] product bears no expiration date and the [redacted] product bears the expiration date on the bulk container. You indicated to Investigator Andrews that you were unaware that stability testing was required for repacked liquid products.

You could provide no documentation or records to indicate that the general repacking area and equipment area utilized in the repacking of dispense medication are appropriately cleaned between uses. This is of particular concern due to the observation that you have repacked penicillin and cephalosporin products in this area. Your records indicated that penicillin and cephalosporin products were repacked [redacted] times between January 21 and June 27, 1997. There were no procedures available indicating any specialized handling or cleaning associated with these products. The cleaning logs maintained for the packaging area were noted to be incomplete. Numerous repacked lots were noted not to be included in the logs reviewed.

The above deviations were included on the FDA 483 (Inspectional Observations) which was issued to and discussed with Steven B. Hauck, President, at the conclusion of the inspection. The violations noted in this letter and in the FDA 483 are symptomatic of serious underlying problems in your firm's repackaging and quality assurance systems. The recall of mislabeled product and the other instances we encountered of mislabeled product you have distributed, could be directly attributable to these observations. Due to the nature and scope of the problems encountered by Investigator Andrews, we would strongly encourage you to immediately contact this office to set up a mutually agreeable time so that we may discuss our ongoing concerns with the lack of control in your facility.

We are in receipt of the letters you issued on July 23 in response to the inspection. The letters express a continued confusion as to what regulations pertain to your operation even though you have been associated with similar repackaging operations for years and have been previously inspected by FDA. You are attempting to compare your Dispense-Med operation to a pharmacy. Your facility (including the "Dispense-Med section) is a repackaging operation and you must comply with the applicable requirements and implement the above discussed controls. In light of the type of significant mixups reported to you by [redacted] we would think you could understand the need for increased scrutiny in the Dispense-Med operation. The Dispense-Med operation is of particular concern based on the significant observations encountered. One of the topics we would want to discuss with you at our meeting would be what steps you have taken to assure that the serious mixups reported by [redacted] were not encountered in products distributed to your other customers.

The deviations discussed above and included on the FDA 483 should not be construed as an all inclusive list of violations which may be in existence at your firm. It is your responsibility to ensure adherence to each requirement of the Act. You are responsible for investigating and determining the causes of the violations identified by FDA. You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response should address any proposed actions regarding products currently in distribution which may have been mislabeled. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. You may call Mr. Campbell at (404) 347-3162 to set up the meeting discussed above. We anticipate that you will contact Mr. Campbell by telephone within five (5) days of receipt of this letter.

Sincerely,

for Roger E. Kline

Ballard H. Graham, Director
Atlanta District